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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,481	08/25/2008	Matthew Buderer	OSLER1140-1	9925
28213	7590	12/27/2010	EXAMINER	
DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,481	Applicant(s) BUDERER ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-9 and 18 in the reply filed on 11/04/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse talcs and clays as the binding carrier and shea butter as a plant oil or wax in the reply filed on 11/04/2010 is acknowledged. The traversal is on the ground(s) that searching for all of the binding carriers and the plant oils or waxes would not constitute a serious burden and that a selection of binding carriers and plant oils/waxes is preferred. This is not found persuasive because the carriers and plant oils and waxes are distinct species and a search for one is not co-extensive with a search for each and every other specie, particularly with regards to the plant oils and waxes. The requirement is still deemed proper and is therefore made **FINAL**. Please note that all of the claims in Group I, except for claim 5, are being examined because talc and clay include a silicate and a magnesium, since clay is magnesium aluminum silicate the species election remains for reasons of record.

Claims 5, 19-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/04/2010.

Claims 1-4, 6-9 and 18 are currently being examined on the merits.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 1/23/2008 and 11/10/2009 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

The information disclosure statement filed 1/24/2008 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the IDS is a duplicate of the IDS submitted on 1/23/2008. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

The IDS dated 1/24/2008 was crossed out because it is a duplicate of the IDS filed on 1/23/2008 and the references were only considered once. Any reference with a line through it was not considered because Applicant did not provide a translation of either the abstract or the whole reference.

Claim Objections

Claim 2 is objected to because of the following informalities: the term “cream” is misspelled in line 2. Appropriate correction is required.

Claim 6 is objected to because of the following informalities: the term “a salicylates” and “a silicates” is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of claim 1 are uncertain because it is unclear as to what Applicants mean by “consisting of” in line 2 of claim 1. The language “consisting of” is closed claim language. However, Applicants claim additional ingredients in the dependent claims, which renders the claims indefinite. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Therefore, the claims will be examined as if they contain the open claim language, “comprising”, since the composition currently contains additional ingredients.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Xiong et al. (A, 6299925 B1).

Xiong teaches a solid-state water soluble granular or tablet formulation comprising green tea plant extract containing polyphenols in an amount of 5-99 wt% (which reads on polyphenol, as defined by Applicant in Applicant's specification- see page 5 as an example), wherein the tea plant extract is first combined with a lubricant, wherein the lubricant can be polyethylene glycol 6000 or sodium lauryl sulfate (which reads on topical gel, since it is a gel and can be applied topically) or sodium benzoate (which reads on polyphenol in an anhydrous mixture) and a binder, wherein the binder can be starch (which reads on adsorbent binding carrier), celluloses, gelatin or guar gum, prior to combination with other ingredients. Xiong teaches that the combination of green tea plant extract and the binder does not require water (which reads on anhydrous) and can further include other anhydrous materials, such as citric acid and carbonate salts.

Although Xiong does not expressly teach that the tea plant extract is adsorbed onto the binding carrier, the claimed functional properties are inherent to the preparation taught by Xiong because the ingredients and the formulation of the ingredients taught by Xiong are one and the same as disclosed in the instantly claimed invention of

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Applicant. Thus, the tea plant extract containing polyphenols in the presence of a lubricant would inherently be adsorbed onto a binding carrier as taught by Xiong.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiong et al. (A, 6299925 B1), in view of Hall et al. (N, WO 03063840 A2, Abstract only).

The teachings of Xiong are set forth above and applied as before.

Hall teaches a pharmaceutical composition comprising an antacid core comprising a water impermeable film comprising shea butter. Hall further teaches that the composition can comprise talc and magnesium aluminum silicate (which is synonymous with clay and also reads on a magnesium and a silicate as a binder).

It would have been obvious to modify the anhydrous effervescent composition taught by Xiong by combining polyphenols extracted from tea adsorbed on a binding carrier and gel that can be administered topically taught by Xiong with talc or the clay binder taught by Hall and further combining the adsorbed tea polyphenols with shea butter by Hall because at the time the invention was made, it was known that tea polyphenols could be combined with a binding carrier in an effervescent composition, as clearly taught by Xiong and that clay is a useful as binder in an effervescent composition and that shea butter can also be used in an effervescent composition to help form a water impervious layer as clearly taught by Hall.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. Based on the disclosure by that tea polyphenols can be combined with a binder and a topical gel as clearly taught by Xiong, and that clay can be used as a binder in an effervescent composition and that shea butter can be used in an effervescent composition as taught by Hall, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of

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known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Thus, an artisan of ordinary skill would reasonably expect that modifying the anhydrous effervescent composition taught by Xiong by combining polyphenols extracted from tea adsorbed on a binding carrier and gel with talc or the clay binder and shea butter would provide an even more effective anhydrous effervescent composition, because shea butter is known to be useful as a barrier against moisture to help maintain the life of the effervescent tablet based upon the teachings of Xiong and Hall. This reasonable expectation of success would motivate the artisan to modify the anhydrous effervescent composition taught by Xiong by combining polyphenols extracted from tea adsorbed on a binding carrier and gel with talc or the clay binder and shea butter based upon the teachings of Hall.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/
Primary Examiner, Art Unit 1655